



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SB 493 IMPLIMENTATION COMMITTEE MEETING
MINUTES**

DATE: June 4, 2014

LOCATION: Rancho Los Amigos Rehabilitation Center
7601 E. Imperial Highway
Downey, CA 90242

COMMITTEE MEMBERS

PRESENT: Stanley C. Weisser, President, Committee Chair
Deborah Veale, RPh
Amy Gutierrez, PharmD.

COMMITTEE MEMBERS

NOT PRESENT: Victor Law, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Michael Santiago, DCA Staff Counsel
Laura Hendricks, Staff Analyst

Call to Order

President Weisser called the meeting to order at 9:08 a.m.

President Weisser opened the meeting with a brief statement: The purpose of the committee is to allow board members to give their undivided attention to the implementation of SB 493. He said it is critical that as the board goes forward with implementation that it is done right the first time so the board does not have to make major changes down the road.

President Weisser noted that he took his time picking the committee members and considered the expertise that each member will bring to the process. He added that he purposefully kept the committee small so that it could remain agile.

Since the passage of SB 493, many groups have been working on the implementation, the committee looks forward to their input; however, it is important to remember that the responsibility for implementation is solely the board's. President Weisser concluded that he expects the committee to meet more often than other board committees and he hopes that the committee can make a final recommendation to the full board by the end of 2014.

President Weisser conducted a roll call. Committee members present: Amy Gutierrez, Deborah Veale and Stanley Weisser. Committee member Victor Law was absent.

1. Overview of Elements of SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser asked Executive Officer Virginia Herold to give an overview of SB 493.

Ms. Herold provided an overview of SB 493 as follows:

For pharmacists who become specially licensed as advanced practice pharmacists:

- Creates a new license category of advanced practice pharmacist who may practice advanced practice pharmacy within or outside a pharmacy.
- Allows an APP to possess controlled substances
- Allows an APP to:
 - Perform patient assessments
 - Order and interpret drug therapy related tests
 - Refer patients to other health care providers
 - Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
 - Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter information into a patient record, shared with the prescriber
 - require registration with DEA for prescribing APP
 - tests ordered by APP in coordination with and notification to patient's diagnosing physician
- Requirements to become an APP:
 - Hold an active CA pharmacist license – in good standing
 - File an application with the board and pay a fee. The board did a cost analysis and determined that a \$300 fee would cover the board's costs.
 - License will be good for 2 years linked to pharmacist license renewal
 - An additional 10 units of CE are required each renewal cycle in an area of practice relevant to the pharmacist's clinical practice
- Qualifications: possess 2 of the 3 below:
 1. Earn certification in a relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy,

- psychiatric practice recognized by ACPE or another entity recognized by the board)
2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
 3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management or health system.

For all licensed pharmacists:

- Adds a determination that the Legislature declares pharmacists are health care providers who have the authority to provide health care services.
- Allows a pharmacist to administer drugs and biological products that have been ordered by a prescriber.
- Allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older.

To initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC
- be certified in basic life support
- comply with all state and federal recordkeeping requirements,
- provide information to the patient’s primary care physician and into the CDPH’s immunization registry.

A pharmacist may initiate and administer epinephrine or diphenhydramine by injection.

Note: pharmacists that do such immunizations need to be certified to perform these functions.

- Pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications)
- Once a protocol is developed by the Board of Pharmacy and Medical Board of California:
 1. Allows a pharmacist to furnish nicotine replacement products in accordance with a state treatment protocol, provided:
 - Records are retained of drugs and devices furnished for at least 3 years so as to notify health providers or permit monitoring of the patient
 - The pharmacist notifies the patient’s primary care provider of drugs and devices furnished or into a patient record
 - the pharmacist must complete 1 hour of CE on smoking cessation therapy biennially
 2. Pharmacists may furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Board and the Medical Board of California pursuant to the guidelines of the CDC.

Public Comment

There were no comments from the public or from the committee.

2. Use of “Advanced Practice Pharmacists” in Other States

President Weisser reported that at least three states have some experience with a version of advanced practice pharmacists. They are New Mexico, North Carolina and Montana. General information about the scope of services authorized to these pharmacists was provided in the meeting materials.

President Weisser noted that the programs in other states rely heavily on the oversight of the Medical Board; while in California, SB 493 gave the Board of Pharmacy this responsibility. President Weisser stated that this responsibility demonstrates how important it is for the committee to implement a program that meets the high standards that are expected.

Public Comments

There were no comments from the public or from the committee members.

3. Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:

- (a) For Pharmacists who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices**
- (b) For Prescription Medications not Requiring a Diagnosis that are Recommended by the CDC for Travel Outside the US**
- (c) For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies**

President Weisser stated that the meeting materials contained a wealth of information on this agenda item. President Weisser asked the committee members if there was a section (a, b or c) that they would like to discuss. The committee did not comment so President Weisser opened the floor to the public.

Public Comment

Felix Pham, clinical pharmacist, noted that some of the APP qualification methods seemed to overlap, particularly in regards to becoming certified in a certain area of practice and completing a certain number of experience hours. Ms. Herold responded that the overlap of the qualification methods is something that this committee will have to discuss and resolve.

Dr. Steve Gray, representing CSHP and Kaiser, commented that there are currently 47 states that have some sort of collaborative drug therapy management where pharmacists can prescribe and order tests - including California. Dr. Gray commented that the board should look at other states to learn what problems could be avoided. Dr. Gray concluded that SB 493 was created to give better access to healthcare, and Kaiser as well as other organizations are willing to help the board in any way needed. The committee noted that the board will have to find a

balance that creates a high standard for APPs, but is not so limiting that it defeats the intended purpose of SB 493.

Dr. Dan Robinson, dean of Western University, commented that what he likes most about SB 493 is the independence that it gives pharmacists in that they were given provider status. He added that SB 493 allows pharmacists to practice at the full scope of their knowledge and experience and increases their involvement in direct patient care. Ms. Veale and President Weisser agreed that gaining provider status was an important piece of SB 493 as it potentially will allow pharmacists to be reimbursed by insurance companies for their services. Ms. Herold noted that the board cannot secure or advocate for reimbursement, that will be up to pharmacists.

Dr. Robinson asked to clarify if a year of residency can also count towards a year of direct patient care experience. He noted that perhaps the committee could look at how North Carolina interpreted this requirement. President Weisser responded that this would be an important point for the committee to discuss.

Larry Lovett, from Long Beach Memorial Hospital, noted that “travel medications” is very broad and asked if the Legislature had intended it only for the use of travel immunizations or if it went beyond that scope. Ms. Herold responded that the way the bill is written it includes both immunization and other medications you may need while traveling such as antibiotics or anti-nausea medications. Ms. Herold noted that the CDC has extensive resources available online on its website.

Mr. Lovett stated that as furnishing travel medications is something that all pharmacists can now do (not just those with an APP license) the committee may want to consider creating extra protocols in this area. Mr. Gupta, pharmacist, agreed that additional protocols should be in place as pharmacists are not doctors and employers may force pharmacists to provide these services without proper support or training. Ms. Herold responded that anytime a pharmacist is asked to do something that is beyond their training or knowledge it is the pharmacist’s professional obligation to refuse. She added that this may mean a pharmacist needs to find another employer. Dr. Gutierrez added that it is a difficult position for pharmacists to be in if they want to keep their job. Ms. Veale commented that large chain pharmacies will likely be hesitant to force this type of service without proper training and protocols as they can face lawsuits if a patient is harmed.

Mr. Lovett commented that many pharmacists in California, particularly those in acute care settings, already perform many of the duties described in SB 493. He asked if those pharmacists will now have to become licensed as an APP in order to keep working as they have done for years. Ms. Herold responded that SB 493 did not change any of the existing provisions and they can continue to work under these provisions without becoming licensed as an APP.

Dr. Gray, representing CSHP, commented that SB 493 was created to alleviate overburdened health care professionals (doctors and nurse practitioners). For example, a patient does not

need to be diagnosed by a doctor to receive travel medications for a trip to Africa or to use nicotine cessation products to quit smoking. Dr. Gray noted that it is important to remember that there is a difference between furnishing and prescribing.

President Weisser asked the public if there was anyone who could give the committee additional information on the injectable portion of travel medications. Jeff Goad, from Chapman University, reported that the way SB 493 was written, independently initiated travel vaccines were not technically included. However, as the protocol provision was left untouched, a pharmacist can still provide ACIP routinely recommended travel vaccines, as long as they do so under protocol, which still requires physician involvement. Ms. Herold commented that the committee will take a look at the language and determine if they agree with that interpretation.

Dr. Goad reported that approximately 5 percent of the traveling population sees a healthcare professional before traveling. SB 493 makes the process of getting travel medications much easier in a travel clinic setting, something that has been historically difficult due to protocol requirements. Dr. Goad noted that he would be opposed to creating a protocol for travel medications as things can change overnight based on outbreaks and protocols would considerably slow the process. Dr. Goad commented that he does recommend training and education for travel medicine. He added that he was surprised to see that there are requirements for smoking cessation and oral contraception, but not for travel medication.

Dr. Goad reported that the law does specifically mention the CDC's recommendation for international travelers, otherwise known as "the yellow-book." The yellow-book is a good reference for pharmacists to determine what medications are recommended for international travel. Ms. Veale asked how often this book is updated. Dr. Goad responded that the book is updated once a year, however, the CDC sends out notices of outbreak information so that practitioners can make adjustments based on current international situations.

President Weisser asked if there are existing programs that could provide training for pharmacists. Dr. Goad responded that APHA does have a program and other universities may also be creating programs.

Dr. Kathleen Hill-Besinque, from USC and CPHA, commented that she looked up the definition of "furnish" in the law book and it does not say that it must be a medication that the pharmacist has on the shelf. The definition says "by any means" so a pharmacist could write a prescription so the patient could go somewhere else to get the medication.

Dr. Hill-Besinque, asked the board to consider curriculum-based training, rather than requiring containing education training classes. Ms. Herold asked how the board could ensure that the curriculum at each school was providing similar information to ensure that students are really graduating with adequate knowledge. Dr. Hill-Besinque commented that Hawaii allows for curriculum equivalent training in contraception, so she writes a letter to the Hawaii board stating that the student had the training and how many hours they received. Dr. Gutierrez asked how long this training has been a part of USC's curriculum. Dr. Hill-Besinque responded

since 2000. The committee noted that they may need to consider graduation date when accepting curriculum based training. Ms. Herold commented that the board will need some way to verify that a student received the training.

Dr. Gray, commented that the committee should also look outside of California to see what kinds of training universities on the East Coast provide for travel medications, as they serve a population that frequently travels overseas.

Robin Corelli, from the University of California, San Francisco, commented that since 2000 all California schools of pharmacy graduates receive an average of 6.5 hours of education on smoking cessation education as part of the core curriculum.

Mr. Rajesh Gupta, pharmacist, commented that he does not feel that pharmacists, particularly in chain stores, should do travel immunizations as they have not received training. He also added that as a recent graduate, he did not receive any training on smoking cessation. President Weisser asked if he was a graduate of a California school of pharmacy and Mr. Gupta responded that he was a graduate of a Rhode Island school of pharmacy.

Ms. Veale asked Mr. Gupta that if training was provided would he still feel a protocol would be necessary for travel medications. Mr. Gupta responded that he still feels protocols should be in place. Ms. Veale commented that with travel medications things can change very quickly and a protocol may make it very difficult for a pharmacist to provide care if a rapid change is needed. However, if training was provided pharmacists could use their education to very quickly modify their care based on new travel information. Mr. Gupta stated that without a protocol employers could force pharmacist to provide travel medications even if they are not comfortable doing so. Ms. Herold stated that if you are not willing to walk away from an order that could potentially harm a patient, you should not be a health care professional.

Dr. Sally Rafie, University of California, San Diego, commented that developing a very detailed protocol for travel medication may not be necessary as the CDC already has information that the board could leverage. Dr. Rafie expressed her support for curriculum based training for oral contraception and smoking cessation as opposed to a CE based training. Dr. Gutierrez asked if the schools provided any documentation for students when they complete the training. Dr. Rafie responded that UCSD currently provided certification to students. Dr. Gutierrez asked how long the schools feel that curriculum-based training should be valid before they need subsequent training. Dr. Hill-Besinque commented that legally there is not a time limit; however as a healthcare professional they should update their knowledge if they are providing care.

Dr. Lisa Kroon, Department Chair for Clinical Pharmacy at the University of California, San Francisco, expressed her support for curriculum based training. She added that the schools should provide the board with information on the content of the training they provide in the curriculum. President Weisser asked how long after graduation would she recommend allowing curriculum-based training to be valid. Dr. Kroon commented that as long as the person is a

practicing pharmacist who is maintaining their CE, the curriculum-based training should be valid for as far back as the school could provide documentation.

Jon Roth, CEO of CPHA, encouraged the board not to implement rigid protocols. The passage of SB 493 illustrated that both lawmakers and the medical profession feel that pharmacists possess the professional knowledge, skills and training to provide patient care. Mr. Roth added that the board would need to have documentation that the curriculum based training occurred so they could validate that the pharmacist was operating within the guidelines of the training.

President Weisser asked Mr. Roth how CPHA feels about the board requiring content-specific continuing education. Mr. Roth responded that they oppose this requirement as it should be the responsibility of the health care professional to determine what CE they need to provide patient care. President Weisser commented that he is always surprised about how many people are discovered to have not completed the required CE when the board audits their renewal applications.

The committee discussed whether a pharmacist should be required to complete ongoing CE in smoking cessation, hormonal contraceptives and travel medications; or if they would just have to provide documentation of initial training in the area and then use their professional judgment to complete CE as needed. Felix Pham, pharmacist, commented that he would support a one-time training verification.

Michelle Tenerelli, Rite Aid pharmacist, commented that she would encourage the board not to create additional protocols. However, as an employer for a chain pharmacy she would support training programs, as a company is responsible anything a pharmacist does while working for them. She added that in California five Rite Aid locations provide travel medication services and the pharmacists all receive training and have resources available to them.

Mr. Rajesh Gupta, pharmacist, commented that he does not feel that curriculum-based training is sufficient and encouraged the board to require additional CE in those areas only for pharmacists who choose to provide the services in SB 493.

Dr. Hill-Besinque commented that in regards to emergency contraception she feels that the board could create protocols as long as they were not too prescriptive and referenced the CDC guidelines. Referencing the CDC guidelines would allow for the protocols to remain current without having to go through a long process every time there was an update at the CDC. Dr. Hill-Besinque added that curriculum-based training provided better education than most continuing education courses.

Three Western University School of Pharmacy students provided the committee with insight into the type of education they have received during pharmacy school. They all expressed that they would feel comfortable in providing patient care in smoking cessation, hormonal contraception and travel medicine based on the education they have received in school.

The committee recessed for a break at 11:05 a.m. and resumed at 11:20 a.m.

Ms. Tenerelli, asked if pharmacists who attended school prior to the time when ACPE started endorsing schools of pharmacy would need to be re-trained. Ms. Herold confirmed they would. President Weisser commented that the previous discussion had covered multiple agenda items and asked that the committee return to agenda item 3(c) - Ordering and Interpreting Tests to Monitor and Manage Drug Therapies.

CSHP created a committee to develop guidelines for ordering and interpreting tests after the passage of SB 493. The committee created draft guidelines for the board to review. President Weisser thanked CSHP for their work and reminded the public and the committee that the responsibility for the implementation of SB 493 ultimately fell to the board.

Robert Deamer, a member of the CSHP committee, provided the committee with highlights from the guidelines they created as follows:

Note: The committee and the audience were provided with copies of the entire guideline document at the meeting. This document can be found immediately following these meeting minutes.

CSHP Draft Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy

The purpose of this guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose of monitoring the efficacy and safety of drug therapy. Specific objectives are as follows:

- Establish best practices for pharmacists ordering and managing tests in the course of monitoring and managing the efficacy and safety of medication therapy in collaboration with the patient's primary care provider, diagnosing prescriber, medical home, etc. The priority of these best practices is to ensure that test ordering by pharmacists is performed only when necessary and that results are managed appropriately and promptly. These best practices are based on research, government reports, and decades of combined experience from California and other states.
- Provide resources to educate other healthcare professionals, testing organizations, health plans, and other third party payers about the role of pharmacists in ordering and managing tests in coordination with primary care providers and other members of the healthcare team.
- Describe payment models for test ordering by pharmacists.

Key principles for test ordering, interpretation, and management by pharmacists are:

- Testing should be for ensuring safe and effective medication therapy in coordination with the patient's primary care provider or diagnosing prescriber.
- Tests must only be ordered when necessary.
- Test results must be managed appropriately and promptly;
- Patients should receive feedback on their tests in a timely manner.
- Quality assurance should be integrated into the test ordering, interpretation, and management process.

Responsibility: Pharmacists are individually responsible for personal competence in ordering tests and interpreting results. Variables that may impact test results must be considered by pharmacists when interpreting results including timing of testing, medications, renal or hepatic function, fluid status, lab error, etc.

Using test results: In situations where tests could impact medication therapy decisions or medication therapy might alter testing results, pharmacists should review relevant tests that are required to make this determination. If required tests are not available, e.g., tests that are mandated in current treatment guidelines, FDA recommendations, or medication prescribing information, then the pharmacist should consider ordering or facilitating the ordering of these tests in collaboration with the relevant medical entity.

Ordering tests:

- If specific tests are important for determining the appropriateness, efficacy, or safety of medication therapy and test results have not been previously ordered or are out of date then pharmacists should order the tests or follow the procedure within their collaborative practice to ensure that the appropriate test is ordered.
- Pharmacists must pursue all reasonable approaches to ensuring that tests are not duplicative prior to ordering, e.g., review of the electronic health record, contact with test technician if such a line of communication is available. An exception is when a result is questionable and warrants a repeat test (e.g., abnormal potassium level and suspected hemolysis of blood sample based on previous test results).
- Pharmacists should only order those tests that they are personally competent to order; otherwise, an appropriate authority should be consulted.

- Tests must be necessary (e.g., per treatment guidelines, government mandates, prescribing information; clinical evaluation requirement) and limited to patients under the care of the pharmacist / pharmacy service.

Interpretation of test results:

- Pharmacists should only order tests that they are experienced in interpreting. An exception is when a test is necessary and, in a pre-arranged collaboration, the test is ordered but planned for interpretation by a qualified healthcare professional.
- Pharmacist must use professional judgment and consider all variables when interpreting test results.

Following-up on test results:

- Pharmacists who order tests must have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc.
- Patients should be informed of what to expect by having the pharmacist order tests, e.g., who will follow-up and how soon.
- If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.
- Pharmacists must take appropriate action if the result of a lab test ordered is a critical value, defined as, "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken".
- At minimum, a pharmacist who receives a critical value should contact the physician responsible for the care of the patient at the time of notification.

Standards for documentation:

- As required by SB 493, all actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) must be documented within 24

hours in a system readily accessible to all involved healthcare team members involved.

President Weisser asked Mr. Deamer how he would define “coordination” between a pharmacist and physician. Mr. Deamer responded that communication is key. The electronic system in place in many health care systems makes this communication between health care providers much easier.

Dr. Gutierrez asked to clarify if any pharmacist could order test or if it is only something that an APP pharmacist can do. It was confirmed that any pharmacist could order and interpret tests, not just those who have APP licensure. Mr. Deamer commented that doctor groups were hesitant about pharmacists ordering and interpreting tests. The challenge was to show that pharmacists have the knowledge and skills needed, and especially in the case of drug therapy management, excel at interpreting results.

Ms. Herold asked if there was no primary care provider could a pharmacist still order tests. Mr. Deamer responded that the pharmacist could refer the patient to a physician within the health system or in the community. He added that the pharmacist may need to refuse to order a test until the patient is seen by a physician. Ms. Herold noted that the committee needs to consider that a patient may change physicians without telling their pharmacist.

Dr. Gutierrez expressed concern that the pharmacist may order tests that result in the need for a diagnosis, which would need to be handled by a physician, not the pharmacist. Ms. Veale commented that she envisioned pharmacists ordering tests that would determine the effectiveness of a drug therapy, not a new test used to diagnose. She added that if a test the pharmacist ordered did reveal a problem that needed diagnosis, it would be the responsibility of the pharmacist to contact the physician and discuss it with him or her. Dr. Gutierrez stated that she is not as concerned about pharmacists who are practicing within a health system being able to contact the physician if a diagnosis is needed; rather pharmacists who are practicing independently. Ms. Veale responded that as a health care provider, the pharmacist should do what he or she needs to do to contact the physician. Ms. Herold reported that for years pharmacists have been able to order tests to evaluate drug therapies, however SB 493 gives them autonomy previously not allowed. She concluded that the committee will need to address this new autonomy.

Jon Roth clarified that SB 493 allows all pharmacists to order and interpret tests *only* for efficacy and toxicity related to a drug therapy. An APP pharmacist is allowed to order and interpret tests related to drug therapy. Mr. Roth said the language sets two different requirements for regular pharmacists and APP pharmacists. President Weisser asked if there is any concern with patients diagnosis shopping. Mr. Roth responded that as at least in the near future, patients will have to pay out-of-pocket for these tests and he does not see much incentive.

Ryan Gates, clinical pharmacist, commented that historically pharmacists have not had access to critical information related to patient care. SB 493 is intended to give the pharmacist more information and make the pharmacist part of the medical team. Mr. Gates noted that in securing enactment of SB 493, the sponsors were very careful to use language that required the pharmacist to coordinate testing with the primary care provider to eliminate redundant testing.

A compounding pharmacist specializing in hormone replacement therapy commented that ordering and interpreting tests for drug efficacy is already a common practice with compounding pharmacists. She described how collaboration between the patient, pharmacist and physician occurs in her practice.

Dr. Robinson, Dean of Western University, commented he would estimate that about 70 percent of the curriculum in schools focuses on drug therapy management. SB 493 gives pharmacists access to lab testing to allow them to effectively monitor the drug therapy for patients. Dr. Robertson added that he does not think that testing should be limited to only pharmacists who work in a health system.

John Simimi, acute care pharmacist, commented that he feels there should be a strong protocol in place regarding testing. Ms. Veale said she would prefer there not be a protocol for everything that a pharmacist does, as it could minimize the effectiveness of the new law's provisions.

The committee discussed issues that may arise regarding payment for testing as insurance companies adjust to pharmacists having provider status.

Dr. Gray, CSHP, reminded the committee that SB 493 was created to address the health care shortage. He added that during the development of the bill, physicians asked that pharmacists be allowed to order tests to evaluate a drug therapy so that they can make recommendations about patient care based on objective results.

Dr. Gray commented that the language was specific to say "testing" rather than "lab testing" so that pharmacists could order tests like X-rays to monitor for osteoporosis. He added that pharmacist will now be able to order tests to determine if a patient has opioids in his or her system. If the results show that there are no opioids in a patient's system, then it could point to the patient possessing the drug to sell to others.

Sarah McBane, UCSD and a pharmacist licensed in North Carolina, commented that protocols could potentially overly restrict the pharmacist and harm patient care.

Mr. Gates commented that if test results come back showing there are critical, potentially life threatening problems, the pharmacist may not discontinue the drug therapy but should at least hold the prescription until the pharmacist can talk to the physician. He added that a pharmacist may even send the patient to the emergency room for immediate treatment if the results are serious enough.

Andrew Lowe, clinical pharmacist, commented that he sees many patients who regularly switch primary care providers. To address this, his employer requires asking the patient to confirm if the patient is still seeing the last physician the pharmacy has on record as part of every consultation.

The committee recessed for a break at 12:24 p.m. and resumed at 1:21 p.m.

4. Discussion on Application Requirements of the Advanced Practice Pharmacist License

(a) Board of Pharmacy Specialties Certification Programs

At the request of President Weisser, Ms. Veale briefly reviewed the presentation that Brian Lawson and Andrea Ianucci, from Board of Pharmacy Specialties (BPS), gave at the February 12, 2014 Licensing Committee meeting.

Megan Coder, consultant for BPS, described the qualification process for taking the BPS exam.

Ms. Coder commented that the BPS program is not accredited by ACPE. However the continuing education that BPS offers is accredited by ACPE.

Ms. Coder reported that BPS recently added two specialties: Critical Care and Pediatrics. She added that any organizations that would like to see additional specialties added they could petition BPS.

President Weisser asked Ms. Coder if all of the BPS tests offered are psychometrically sound. Ms. Coder responded that all of the tests are psychometrically validated across the United States; this is ensured by an independent vendor.

Ms. Veale commented that while BPS is a great program, the committee hopes that there will be additional avenues available for licensees.

Dr. Gutierrez asked what the difference is between the BPS program and a certificate program. Ms. Coder and Dr. McBane explained that a certificate program is a one-time class that usually lasts about 15 hours and has no ongoing education once the class is completed. They added that programs like BPS require extensive continuing education.

(b) Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy)

Mr. Tom Clark, from the Commission for Certification in Geriatric Pharmacy (CCGP), provided the board with a presentation on its program. Below is an overview of the presentation, the entire PowerPoint can be viewed following these meeting minutes.

Commission for Certification in Geriatric Pharmacy (CCGP)

CCGP

- Board certification examination in geriatric pharmacy practice
- Certified Geriatric Pharmacist (CGP) credential
- Established in 1997 by American Society of Consultant Pharmacists

Accreditation

- CCGP is accredited by the National Commission for Certifying Agencies
- NCCA is the nationally recognized accrediting body for certification organizations and establishes standards
- NCCA accredits in a wide variety of nursing, health care & other industries
- CCGP is accredited by the National Commission for Certifying Agencies
- NCCA is the nationally recognized accrediting body for certification organizations and establishes standards
- NCCA accredits in a wide variety of nursing, health care & other industries

CCGP Overview

- About 2,500 Certified Geriatric Pharmacists today
- About 40 percent in LTC and about 40 percent hospital-based
- About 10 percent community pharmacy
- About 6 percent managed care, 7 percent academia

Recognition

- Australia – CGP credential recognized by Australian government as one of two pathways for pharmacists to qualify for payment for HMR and RMR
- North Carolina – CGP credential recognized as one of qualifications for Clinical Pharmacist Practitioner
- Missouri – CGP credential recognized as one of the eligibility criteria for pharmacists to qualify for “certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient’s medication therapy or device usage.”

Development

- CCGP test partner is Applied Measurement Professionals (AMP)
- CCGP has Exam Development Committee to work with AMP on test development – rigorous standards

Administration

- CCGP exam is computer-based and administered in four test windows throughout the year
- AMP has network of test centers throughout the U.S., including 16 test centers in California
- Exam is 150 multiple-choice questions and takes three hours

Eligibility

- Current active pharmacist license
- Two years of experience as pharmacist
- Passing score on CCGP examination required to become Certified Geriatric Pharmacist

Recertification

- Certification cycle is five years
- Recertify by retaking exam or by Continuing Professional Development

- Complete 75 hours of designated geriatric continuing education over five years
- Complete part of CE midway thru cycle

Summary

- CCGP examination is a rigorous board certification examination that meets all applicable quality standards
- The CCGP examination is accessible to California pharmacists with 16 test centers and exam administration throughout the year
- The CCGP examination is particularly well suited to the requirements of the California legislation, with a good match to the CGP content outline

A member of the public asked how many of CCGP certified pharmacists are there in California. Mr. Clark stated that there are about 200 in California.

Ms. Herold asked how many pharmacists recertify after five years. Mr. Clark responded that their recertification rate is about 77 percent.

Dr. Gutierrez asked if the continuing education that is required for recertification is specific to their program. Mr. Clark provided that they require it to be taken through the American Society of Consultant Pharmacists.

Dr. Gutierrez asked what the cost is for pharmacists. Mr. Clark responded that the certification test is \$600 and if candidates pass the exam there is a \$250 administrative fee that covers the whole five years the certification is valid. He noted that there are payment plans available.

Dr. Gutierrez asked if continuing education is included in the \$800 cost. It was confirmed that the continuing education is not included and it is paid directly to the course provider.

A board-certified pharmacist in the audience commented that the cost to become certified and maintain the certification can be a burden to pharmacists.

Dr. Robinson commented that the language in SB 493 states that the certification program must be recognized by ACPE or the Board of Pharmacy. However, ACPE does not recognize certification programs. Dr. Robinson concluded that in the future, perhaps there should be a legislative change to the requirement. President Weisser asked how difficult it would be to change the language. It was noted that an easier solution might be for the board to recognize NCCA as an appropriate accreditation body.

(c) Other Programs Envisioned or Under Development

President Weisser asked the public if there was anyone who would like to discuss other programs.

Eric Gupta, from Western University, brought the Clinical Lipid Specialist Exam to the committee's attention. He noted that while it is mostly taken by physicians, it is available to pharmacists.

Lisa Kroon, from UCSF, highlighted the Certified Diabetes Educator and the American Academy of HIV Medicine as two existing certification programs. Ms. Veale asked if they were both recognized by NCCA. Dr. Kroon responded that she thought they were, but she would need to confirm.

Ryan Gates, clinical pharmacist, commented that after the passage of SB 493 he expects to see more pharmacists becoming certified and feels that pharmacists will come from other states to practice in California. He encouraged the board to be sure that whatever certification program is approved, the program ensures patient safety. Mr. Gates also noted that when the board is considering programs, it should compare the scope of the content of the exam and the scope of the duties and requirements for an APP pharmacist.

Ms. Veale commented that she does not want to have multiple programs petitioning the committee. The committee should create objective criteria that programs must meet to be considered.

Ms. Herold commented that programs should come before the committee similar to how BPS and CCGP have done.

Mr. Veale noted that even if an APP does a one-time certificate course they are still required to complete 10 additional continuing education hours in their specialty area before they can renew their board license.

Mary Staples, from the National Association of Chain Drug Stores, commented that NACDS supports multiple pathways for certification. She provided the committee with a list of certification programs, which can be found immediately following these meeting minutes.

Lisa Kroon commented that there is an online, 20-week program offered by the Canadian Pharmacists Association. The course is practice-based and focuses on patient care skills. The program has a class size of 13-14 pharmacists and has a coach who monitors the learning taking place. President Weisser asked if the program was academically rigorous. Dr. Kroon responded that she found the program to be extremely high quality. Dr. Gutierrez asked if there is a test at the end of the program. Dr. Kroon responded that at the end of the program the student creates an action plan for a complicated sample patient and the plan is graded. President Weisser asked if someone could provide a presentation on the Canadian program.

Dr. Kroon also suggested that the committee consider the use of an Objective Structured Clinical Exam (OSCE). These exams are hands-on and are used in schools of pharmacy and in other medical professions.

Ms. Herold commented that before organizations give presentations on their programs, criteria should be developed by the committee.

Dr. Gray commented that OSCE programs are not standardized and differ depending upon who administers the exam. Dr. Gray agreed that the committee should first develop program criteria before allowing numerous groups to come before the committee. Ms. Herold and Dr. Gutierrez agreed and asked legal counsel to look at the law to see what the board has the authority to require.

Ms. Herold pointed out that there is a requirement in California that all exams must be validated; this might be particularly difficult for OSCE-type exams. Dr. Gray commented that there are currently pharmacists who are doing APP-type work that could be observed to validate tests.

5. Discussion on Renewal Requirements of the Advanced Practice Pharmacist License

Ms. Herold reviewed Code Section 4233 outlining the renewal requirements for the APP license. Ms. Herold noted that currently about 20 percent of pharmacists audited cannot provide proof of their continuing education at the time of renewal. One of the new staff positions the board will be receiving will be responsible for auditing the APP renewals.

Jon Roth, CPHA, commented that it is important to note that the continuing education required for APP renewal must be in the subject area specific to their practice area.

Sara McBane asked how soon the board would have electronic renewals, as other states have online renewals where the pharmacist enters in the ACPE continuing education completion number. Ms. Herold responded that the online renewal date is still uncertain and noted that the board does not require continuing education to be from an ACPE course (for example the board awards C.E. for attending board meetings).

Ms. Herold noted that APP pharmacists will pay their APP and regular license renewal at the same time.

Ms. Veale asked that before the conclusion of the meeting, that the committee review the previous agenda items to develop a work list for the next meeting. The two items below were mentioned and President Weisser asked that Ms. Herold work with legal counsel, Michael Santiago, to determine if there are additional items.

- What criteria, if any, does the board have the authority to develop for certification programs.
- All pharmacists can order tests for toxicity and efficacy of drug therapy, what are the implications of this for the duties of pharmacists? For example, will pharmacists be required to review test results prior to dispensing a particular medication. Does this change their corresponding responsibility when dispensing opioids?

6. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Ms. Herold reported that there would be a one-day board meeting on June 26, focused mainly on the compounding regulation. There will be a two-day board meeting on July 30-31. Ms. Herold reported that July 30 will be the board business day and July 31 will be a mini prescription label summit.

Rajesh Gupta commented that he does not feel that pharmacists should be required to provide consultations to each patient and suggested that if a patient does not speak English, the pharmacist should have the discretion to refuse to fill the prescription. President Weisser noted that the committee could not comment in accordance with the California Law.